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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/644,981 Confirmation No. : 6366
First Named Inventor : Bernd SUNDERMANN
Filed : August 21, 2003
TC/A.U. : 1625
Examiner : C. Aulakh

Docket No. : 029310.52539US
Customer No. : 23911

Title : Substituted Propane-1,3-Diamine Derivatives and
The Pharmaceutical Use Thereof

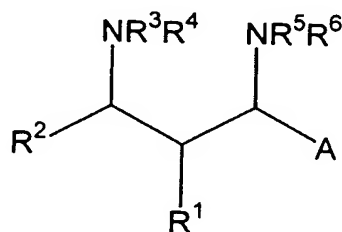
PETITION UNDER 37 C.F.R. §1.144

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The presently claimed invention relates to a group of diaminoalkane compounds having analgesic activity. The claimed compounds are defined by the following formula I:



in which the substituent groups R1, R2, R3, R4, R5, R6 and A have various meanings set forth with greater particularity in claim 1.

In an initial Office Action mailed March 31, 2005, the examiner required restriction of the application to one of twelve groups within the scope of claim 1 defined by the various meanings of the substituents R1 through R6 and A. Applicants submitted a written Reply with a provisional election and a traversal on May 2, 2005. The requirement was repeated and made final in the Office

Action mailed June 21, 2005. Applicants requested reconsideration in their Amendment of October 21, 2005, and the requirement was repeated again in the Final Office Action mailed December 22, 2005. Applicants contend that the restriction fails to comply with controlling law or with the applicable procedures of the Manual of Patent Examining Procedure (MPEP) and hereby petition the Commissioner to exercise his supervisory authority to withdraw the restriction requirement and direct the Examiner to examine Applicants' claims in accordance with the applicable provisions of MPEP §803.02.

Applicants note at the outset that claim 1 is a proper Markush claim which satisfies the test for unity of invention set out in the case of *In re Harnisch* 206 USPQ 300 (CCPA 1980). According to this test, unity of invention exists where the compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility. In the instant case, the compounds of claim 1 (1) share the common utility of analgesic activity, and (2) share the substantial structural feature of Formula I essential to that utility.

It is improper for the Office to refuse to examine a claim which applicants regard as their invention, provided the claimed subject matter exhibits unity of invention. *In re Harnish, supra*. This follows because applicants have a statutory right to define what they regard as their invention. 35 U.S.C. §112, second paragraph. As explained in the case of *In re Weber*:

An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of §112. We have decided in the past that §112, second paragraph, which says in part "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention," allows the inventor to claim the invention as he contemplates it. (*citation omitted*)

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such

action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *In re Weber*, 580 F.2d 455, 198 USPQ 328, 331 (CCPA 1978)

The restriction requirement in the instant case is improper because it is in derogation of Applicants' statutory right to define what they regard as their invention. Moreover, the instant case is a good example of the danger noted in *Weber* that the totality of the fragments would not be the equivalent of the original claim. Here it appears that none of the Examiner's twelve groups embraces compounds in which R2 is a -(C1-6 alkyl)-C3-8 cycloalkyl or a -(C1-6)-aryl group. Moreover, compounds in which R1 and R2 together do not form a ring, R3 and R4 together are -(CH2)2-X-(CH2)2- and R5 and R6 together are -(CH2)o- appear to fall in both groups VIII and IX. Other instances of confusion could be cited, but these should suffice to show that Applicants could be prejudiced if forced to divide up their claim in accordance with the attempted restriction. The attempted restriction raises a real danger that Applicants may not be able to protect the full scope of their invention.

The restriction requirement is also improper because it focuses on the identities of the substituent groups and not on the compounds as a whole. Where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression. See MPEP §2173.05(h) and *Ex parte Taylor*, 167 USPQ 637 (BPAI 1970). Contrary to this principle, the instant restriction divides up the groups based on the identities of the substituents R1 – R6 and A. This is improper and also warrants rescission of the requirement.

It may well be that claim 1 embraces compounds which are patentably distinct from each other. This alone does not, however, justify restriction. MPEP §803.02 explicitly points out that proper a Markush-type claim may include independent and distinct inventions. MPEP §803.02 goes on to set out a detailed procedure to be followed in such a case.

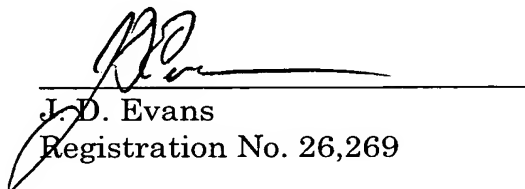
Applicants submit that under the facts of the instant application, the attempted restriction within claim 1 is improper. Instead, the procedure set out in MPEP §803.02 is the proper procedure for examination of the instant claims, and Applicants respectfully petition the Commissioner to withdraw the restriction requirement and direct the Examiner to proceed in accordance with the applicable provisions of MPEP §803.02.

If there are any questions regarding this Petition or the application in general, a telephone call to the undersigned at (202) 624-2845 would be appreciated since this should expedite the prosecution of the application for all concerned.

It is believed no fee is required for this Petition. However, if a fee is required, the Commissioner is hereby authorized to charge such fee to counsel's deposit account no. 05-1323 (Ref. # 029310.52539US).

Respectfully submitted,

March 22, 2006


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